K031193

510(K) SUMMARY

JUL 03 2003

Submitted by:

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Manager, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
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(817) 551-8338 (Phone)
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Device Name:

Common Name: Soft (Hydrophilic) Contact Lens Care Solution

Proprietary Name: OPTI-ONE® Multi-Purpose Solution

Indications for Use:

For use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

OPTI-ONE® Multi-Purpose Solution can also be used as the diluent for OPTI-ZYME® Enzymatic Cleaner.

Description:

OPTI-ONE® Multi-Purpose Solution is a sterile, buffered, isotonic, aqueous solution, containing borates, citrate, mannitol, and sodium chloride with Pationic® and Tetronic® surfactants and edetate disodium 0.05% and POLYQUAD® (polyquaternium-1) 0.0011% preservatives.

Substantial Equivalence:

OPTI-ONE® Multi-Purpose Solution is substantially equivalent in terms of its actions and indications for use to MULTI-PURPOSE SOLUTION ID NO. 81573, approved under P830034/S26 (OPTI-ONE® Multi-Purpose Solution).

OPTI-ONE® Multi-Purpose Solution meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

Safety and Effectiveness:

Cleaning Studies

A laboratory study was conducted with OPTI-ONE® Multi-Purpose Solution. The purpose of the study was to evaluate passive cleaning using no rub regimen with soft contact lenses and its ability to clean laboratory deposited lenses.

Microbiology Studies

A study was conducted to evaluate the performance of OPTI-ONE® Multi-Purpose Disinfecting Solution in a regimen consisting of a 5 second rinse of lenses per side and soaking the lenses for 6 hours. No rubbing step or final rinse step was used. The results show that OPTI-ONE® Multi-Purpose Disinfecting Solution evaluated by the test regimen meets the FDA guidelines and the ISO 14729:2001 Regimen Test Requirements.

Clinical Study

A 90-day clinical study was conducted to demonstrate the safety and efficacy of OPTI-ONE® Multi-Purpose Solution using the modified directions for use. The control used in this study was Bausch & Lomb ReNu MultiPlus® Multi-Purpose Solution used according to its approved rub and rinse labeling. The efficacy of OPTI-ONE® Multi-Purpose Solution (modified directions for use) is clinically acceptable and similar to Bausch & Lomb ReNu MultiPlus® Multi-Purpose Solution used according to its approved label

Biocompatibility Testing

OPTI-ONE® Multi-Purpose Solution meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

OPTI-ONE® Multi-Purpose Solution remains unchanged from the previously approved product (P830034/S26) except for the labeling change revising the directions for use. The labeling changes require no new biocompatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 3 2003

Alcon Research, Ltd.
c/o Ms. Kim Kracke
6201 South Freeway
Fort Worth, TX 76134-0450

Re: K031193
Trade/Device Name: OPTI-ONE® Multi-Purpose Solution (Modified Directions for Use)
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: April 14, 2003
Received: April 16, 2003

Dear Ms. Kracke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031193

Device Name: OPTI-ONE® Multi-Purpose Solution (modified directions for use)

Indications for Use:

For use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

OPTI-ONE® Multi-Purpose Solution (modified directions for use) can also be as a diluent for OPTI-ZYME® Enzymatic Cleaner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K031193

Prescription Use_____ OR Over-The Counter Use X

(Per 21 CFR 801.109)